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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,301	01/25/2002	Mark Chasin	207.1300US	3895

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/057,301	Applicant(s) CHASIN ET AL.	
	Examiner Russell Travers, J.D., Ph.D	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-68, 81, 87 and 89, drawn to a method for providing local analgesia by administering a therapeutic composition of matter containing bupivacaine, carriers and excipients encapsulated in micro spheres.

II. Claims 69-80, 88, 90, 91, 92 and 93, drawn to a therapeutic composition of matter containing bupivacaine, carriers and excipients encapsulated in micro spheres useful for providing local analgesia.

III. Claims 82-83, drawn to a method for providing local analgesia by administering a therapeutic composition of matter containing bupivacaine, various corticosteroid compounds, carriers and excipients encapsulated in micro spheres.

IV. Claim 84, drawn to a method for measuring local anesthetic compound levels in vivo.

V. Claim 85, drawn to a method for measuring local corticosteroid levels in-vivo.

VI. Claim 86, drawn to a method for making a therapeutic composition of matter containing bupivacaine, carriers and excipients encapsulated in micro spheres useful for providing local analgesia.

Claims contained in Groups I-VI are directed to patentably unrelated therapeutic methods, and compositions employing a plurality of patentably distinct compound

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species. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed group to practice the claims of the invention chosen.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

The above delineated inventions differ as unrelated pharmaceutical compositions and methods; and are independent and patentably distinct each from the other. The grouped inventions patentably distinct, a reference which would anticipate, or make obvious, the inventions of groups I-VI would not necessarily obviate or anticipate the inventions in the other group. Examiner must consider the burden posed by examining additional inventions; in view of the numerous distinct searches, and separate independent considerations, required for distinct inventions, such burden is present in the instant case. The searches are not co-inclusive as indicated by the diverse nature of the subject matter, thus, would represent an undue burden on Examiner. One skilled in the art would readily practice the invention of one of the above groups with out infringing and or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully

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capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

Applicant is reminded that upon the cancellation of the claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. 1.48 (b) and by the fee required under 37 C.F.R. 1.17 (h).

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617